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09/973,089

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Marie B. Connett-Porceddu

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07/03/2002

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EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/973,089

Applicant(s)

CONNETT-PORCEDDU ET AL.

Examiner

Stuart Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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Claims 1-55 are pending in the present application.

Claim 3 is objected to for lack of antecedent basis. Claim 3 is dependent on claim 1 which recites "an agent that regulates differentiation". Claim 3 refers to said agent as a means to select transgenic pine cells. The two meanings for the same agent are not congruent.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Applicants claim transformed embryogenic cultures and transformed pine plants of the genus *Pinus* subgenus *Pinus*. The cultures and plants were prepared by the claimed methods. Applicants have not described the DNA that was transformed into said plants or cultures.

The Applicants do not identify structural, genotypic, or phenotypic features unique to the transformed plants or embryogenic cultures. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes

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it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Since the genetic material has not been described by genotype, phenotype, specific structural features or by specific function, the specification fails to provide an adequate written description to support the generic claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 22-23, 28, 31-32, 37, 40, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Wenck et al (1999, Plant Molecular Biology 39(3):407-416).

The claims are drawn to a method for regenerating genetically modified Southern yellow pine plants and hybrids thereof, comprising selecting transgenic embryogenic pine cells in the presence of an agent that regulates differentiation of embryos from embryogenic cells, wherein a selection agent is used. The method includes transformation by *Agrobacterium*.

Wenck et al teach a method of genetically transforming *Pinus taeda* (loblolly pine, a Southern yellow pine species) using *Agrobacterium* and selecting the transformed embryogenic lines using kanamycin as an agent to select transformants and incorporating into the media abscisic acid which acts as an agent to regulate differentiation of embryos from embryogenic cells (page 409, left column, first line and right column, 'Embryo maturation' paragraph,

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respectively). This method produces transformed pine plants as claimed by the Applicant and hence Wenck et al anticipate the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23, 28, 29, 31, 32, 37, 38, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wenck et al (1999, Plant Molecular Biology 39(3):407-416) taken with Rutter et al (1998, U.S. Patent 5,731,204).

The claims are drawn to a method for regenerating genetically modified Southern yellow pine plants and hybrids thereof, comprising selecting transgenic embryogenic pine cells in the presence of an agent that regulates differentiation of embryos from embryogenic cells, wherein a selection agent is used, as well as abscisic acid, polyethylene glycol, and gellan gum. The method includes transformation by *Agrobacterium*.

Wenck et al teach a method of genetically transforming *Pinus taeda* (loblolly pine, a Southern yellow pine species) using *Agrobacterium* and selecting the transformed embryogenic lines using kanamycin as an agent to select transformants and incorporating into the media abscisic acid which acts as an agent to regulate differentiation of embryos from embryogenic cells (page 409, left column, first line and right column, 'Embryo maturation' paragraph, respectively).

Wenck et al do not teach using polyethylene glycol and gellan gum at a concentration of about 3% to 5%, or about 0.5% to about 1.5% .

Rutter et al teach using abscisic acid, polyethylene glycol and gellan gum in their media to enhance transformation and regeneration efficiency (see columns 23 and 24, claims 9 and 10, for example).

Given the recognition of those of ordinary skill in the art of the value of producing a transformed pine plant comprising cocultivating *Agrobacterium* with embryogenic pine suspension-cultured cells and then selecting said cells on media to containing a selection agent to produce transformed plants as taught by Wenck et al, it would have been obvious to modify this method by incorporating the abscisic acid, polyethylene glycol and gellan gum to enhance the efficiency of transformation and regeneration of pine plants as taught by Rutter et al. and determination of the particular concentrations of reagents would have been the optimization of process parameters that would not confer patentable distinction on the claimed invention.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Claims 1-3, 22-28, 31-37 and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wenck et al (1999, Plant Molecular Biology 39(3):407-416) taken with Levee et al (1999, Molecular Breeding 5:429-440).

The claims are drawn to a method for regenerating genetically modified Southern yellow pine plants and hybrids thereof, comprising selecting transgenic embryogenic pine cells in the

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presence of an agent that regulates differentiation of embryos from embryogenic cells, wherein a selection agent is used. The claims are further limited wherein said selection agent is contained in a layer and the transformed pine cells are cultured on a support membrane which is placed over a layer containing a selection agent and the method includes eradicating *Agrobacterium*.

Wenck et al teach a method of genetically transforming *Pinus taeda* (loblolly pine, a Southern yellow pine species) using *Agrobacterium* and selecting the transformed embryogenic lines using kanamycin as an agent to select transformants and incorporating into the media abscisic acid which acts as an agent to regulate differentiation of embryos from embryogenic cells (page 409, left column, first line and right column, 'Embryo maturation' paragraph, respectively).

Wenck et al do not teach culturing cells on a support membrane which is placed over a layer containing the selection agent wherein said layer is filter paper with a liquid medium absorbed therein and the support membrane is prepared from polyester, polypropylene or a liquid permeable fluoropolymer fabric. Wenck et al also do not teach eradicating *Agrobacterium*.

Levee et al teach a method of regenerating transformed pine cells comprising culturing the cells on a support membrane and placing the support membrane over a layer of medium comprising a selection agent which would inherently comprise a thin film of liquid medium and the method also comprises eradicating *Agrobacterium* (page 431, right column, 1<sup>st</sup> paragraph).

Given the recognition of those of ordinary skill in the art of the value of producing a transformed pine plant comprising cocultivating *Agrobacterium* with embryogenic suspension-cultured cells and then selecting said cells on media containing a selection agent to produce transformed plants as taught by Wenck et al, it would have been obvious to modify this method

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by culturing the embryogenic suspension-cultured cell on a support membrane comprising filtering the liquid medium and cells through a filter (i.e. support membrane) supported by a Buchner funnel and then placing the support membrane on medium containing a selection agent and chemical to eradicate *Agrobacterium* as taught by Levee et al, wherein the filter paper would have liquid medium absorbed therein. The motivation to use this method is that large numbers of transformed cells can be processed with a minimal amount of damage to the cells, and the choice of material for the support membrane would be the optimization of process parameters that would not confer patentable distinction on the claimed invention.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Claims 1-3, 22-28, 30-37 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wenck et al (1999, Plant Molecular Biology 39(3):407-416) taken with Levee et al (1999, Molecular Breeding 5:429-440) and Rutter et al (1998, U.S. Patent 5,731,204).

The claims are drawn to a method for regenerating genetically modified Southern yellow pine plants and hybrids thereof, comprising selecting transgenic embryogenic pine cells in the presence of an agent that regulates differentiation of embryos from embryogenic cells, wherein a selection agent is also used. The claims are further limited wherein said agent that regulates differentiation of embryos is abscisic acid which is contained in a layer, and the transformed pine cells are cultured on a support membrane that is placed over said layer.



Wenck et al teach a method of genetically transforming *Pinus taeda* (loblolly pine, a Southern yellow pine species) using *Agrobacterium* and selecting the transformed embryogenic lines using kanamycin (see page 408-409, 'Agrobacterium-mediated transformation' paragraphs).

Wenck et al do not teach culturing cells on a support membrane which is placed over a layer containing the selection agent and abscisic acid.

Levee et al teach a method of regenerating transformed pine cells comprising culturing the cells on a support membrane and placing the support membrane over a layer of medium comprising a selection agent (page 431, 'transformation procedure' paragraph).

Rutter et al teach using abscisic acid in their media to enhance transformation and regeneration efficiency (see columns 23 and 24, claims 9 and 10, for example).

Given the recognition of those of ordinary skill in the art of the value of producing a transformed pine plant comprising cocultivating *Agrobacterium* with embryogenic suspension-cultured cells and then selecting said cells on media containing a selection agent to produce transformed plants as taught by Wenck et al, it would have been obvious to modify this method by culturing the embryogenic suspension-cultured cell on a support membrane comprising filtering the liquid medium and cells through a filter (i.e. support membrane) supported by a Buchner funnel and then placing the support membrane on media containing a selection agent as taught by Levee et al and including in the media abscisic acid as taught by Rutter et al. The motivation to use this method is that large numbers of transformed cells can be processed with a minimal amount of damage to the cells.

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Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 7, 10, 13, 16, 19, 22, 24, 25, 27, 28, 31, 33, 34, 36, 37, 41, and 43 and all subsequent dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation “regulates differentiation”. Applicant has not stated the metes and bounds of the regulation governing embryo differentiation. It has been shown that salts in nutrient media regulate differentiation as does sucrose levels and chemicals that alter the osmotic potential of the media, all of which regulate differentiation. In addition, claim 3 broadens the scope of claim 1 by including selectable markers. It is unclear what is Applicants intentions.

Claims 4 and 13 are indefinite in the recitation “an osmoticum”. All compounds or chemicals exert some force on the water potential of the medium. Applicant is requested to explicitly state the compound or chemical that is used as an agent to alter the osmotic potential.

Claims 7 and 16 are indefinite in the recitation “larger than normal quantities”. This is a relative term and Applicant has not specified what is considered normal and what amount of

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gelling agent would be considered “larger than normal quantities”. Applicant is advised to explicitly state the amount of gelling agent used in the procedure.

Claim 10 and 19 are indefinite in the recitation “less than normal quantities”. This is a relative term and Applicant has not specified what is considered normal and what amount of gelling agent would be considered “less than normal quantities”. Applicant is advised to explicitly state the amount of gelling agent used in the procedure.

Claims 24, 27, 33, and 36 are indefinite, vague and unclear in the recitation “support membrane” since it is unclear what is supported. Therefore, it is unclear what would constitute a support membrane in the claimed method.

Claims 25 and 34 are indefinite in the recitation “thin”. This is a relative term and Applicant needs to explicitly state the dimensions of the layer.

Claims 25 and 34 are indefinite in the recitation “film”. What constitutes a film of liquid medium? Applicant needs to explicitly define this term.

Claims 28 and 37 are indefinite in the recitation “in the presence”. This term is vague and suggests that cells just need to be in the same room with the said agent to be selected. Amending the claims to recite --wherein said transformed cells are cultured on medium containing said agent which is in said gel medium-- will rectify the rejection.

Claims 41 and 43 are indefinite in the recitation “eradication of *Agrobacterium*”. As written, this term implies that Applicant is removing *Agrobacterium* from the face of the Earth. Applicant is advised to amend the claim to read on the *Agrobacterium* that is used in the claimed method.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10-11, 13-17, 19-20, and 22-55 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 12-14, 15, 17, 18, 21, 23, 25, 30, 34, 45, 47, 51, 57, and 63-81 of copending Application No. 09/973088. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are drawn to a method for regenerating genetically modified plants of pine of the genus *Pinus* comprising selecting transgenic embryogenic pine cells in the presence of an agent that regulates differentiation of embryos from embryogenic cells wherein the agent is abscisic acid (ABA), polyethylene glycol (PEG) and gellan gum is used as a gelling agent in quantities above and below an arbitrary amount. The method also calls for the use of a support membrane on which the transformed pine embryogenic pine cells are placed and the support membrane is then placed on a gelled medium, thin film of liquid medium, or filter paper all of which contain the above specified components. The support membrane can be made from polyester, polypropylene and a liquid permeable fluoropolymer fabric. The cells are transformed with *Agrobacterium* which is eventually

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eradicated after the transformation process. The Applicants further claim transformed pine plants and transgenic embryogenic pine cultures.

Claims 1, 12-14, 15, 17, 18, 21, 23, 25, 30, 34, 45, 47, 51, 57, and claims 63-81 of copending Application No. 09/973088 are drawn to a method for regenerating transgenic plants of pine of the genus *Pinus* comprising subjecting pine cells to *Agrobacterium* infection followed by selection of transformed embryogenic pine cells to produce transgenic plants. The method comprises the use of a support membrane made from the same materials as specified above on which the pine cells are placed and the support membrane is then placed on various media containing one or more "culture components" (claim 47) wherein the media is a gelled medium, thin film of liquid medium or filter paper in which is absorbed a liquid medium. The particular components of the media would be the optimization of process parameters. The claims are also drawn to the eradication of *Agrobacterium*. Even though claims 1-8, 10-11, 13-17, 19-20, and 22-55 are not identical to claims 1, 12-14, 15, 17, 18, 21, 23, 25, 30, 34, 45, 47, 51, 57, and 63-81 of copending Application No. 09/973088, they would be obvious for the reasons given above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Kim Davis, whose telephone number is (703) 305-3015.

Stuart Baum Ph.D.

June 13, 2002

**ELIZABETH F. McELWAIN**  
**PRIMARY EXAMINER**  
**GROUP 1800**

